

APPENDIX A: MEDICATION GUIDE REMS

Initial REMS Approval: 02/26/2010

Most Recent Modification: 03/27/2014

NDA 20-711 ZYBAN® (bupropion hydrochloride) Sustained-Release Tablets

Smoking Cessation Aid

GlaxoSmithKline
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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the potential serious risk of neuropsychiatric adverse events associated with the use of ZYBAN.

II. REMS ELEMENTS:

A. Medication Guide

GlaxoSmithKline, in accordance with 21 CFR 208.24, will make the Medication Guide available for distribution to patients. In accordance with Federal Regulations, the currently approved Medication Guide is to be dispensed with each ZYBAN prescription. Therefore, GlaxoSmithKline provides a Medication Guide attached to each unit-of-use bottle (the bottle label contains an attached extended content label containing the Medication Guide text).

Because the Medication Guide is included as part of the primary package for ZYBAN, GlaxoSmithKline has met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

In accordance with 21 CFR 208.24(d), a statement will be included on the container label for ZYBAN to instruct pharmacists to dispense the Medication Guide with each prescription of the product.

B. Timetable for Submission of Assessments

GlaxoSmithKline will submit REMS Assessments to FDA 18 months, 3 years, and 7 years from the date of the initial approval of the REMS (February 26, 2010). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment.

GlaxoSmithKline will submit each assessment so that it will be received by the FDA on or before the due date.